I

103D CONGRESS
1ST SESSION

H. R. 3310

To establish the Barbara McClintock Project to Cure AIDS.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 19, 1993

Mr. NADLER introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To establish the Barbara McClintock Project to Cure AIDS.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Barbara McClintock AIDS Cure Act''.

SEC. 2. ESTABLISHMENT OF BARBARA MCCLINTOCK PROJECT FOR CURING AIDS.

(a) IN GENERAL.—The Secretary of Health and Human Services shall in accordance with this Act establish a project for the purpose of developing a cure for acquired immune deficiency syndrome (in this Act referred to as ''AIDS''). The program may not be administered by

any officer or employee of the National Institutes of Health. Subject to the preceding sentence, the Secretary shall designate an official of the Department of Health and Human Services to be the head of such project, and shall carry out this Act acting through such official.

(b) DEFINITION.—For purposes of this Act, the term ''cure'', with respect to AIDS, means any and all approaches which will ensure a well-functioning immune system and a normal life span with a reasonable quality of life.

(c) CERTAIN REQUIREMENTS.—The Secretary, in carrying out the project under subsection (a), shall ensure that the following requirements are met:

(1) The project shall pursue any and all basic science investigations, based on diverse theories and schools of thought which elucidate the pathogenesis of AIDS.

(2) The project shall identify, based on this work, all promising curatives and to oversee their timely and adequate testing through the extraordinary powers detailed in section 5.

SEC. 3. EFFICIENT AND COOPERATIVE MANAGEMENT OF PROJECT.

(a) IN GENERAL.—The Secretary, in carrying out the project under section 2, shall ensure that the following requirements are met:

(1) The project shall establish one central location for its work. All primary research staff shall work at that location; contributing researchers located around the world shall interact via video teleconferencing, an international computer network, and regularly scheduled face-to-face meetings.

(2) The National Institute of Health's existing AIDS research programs shall be maintained. All National Institute of Health basic science research supplementary to that done by the Project shall be performed cooperatively with the project.

(3)(A) All primary research staff and administrators shall be financially compensated only by the project and may not have conflicts of interests with private organizations (including but not limited to universities, pharmaceutical companies, and private research organizations).

(B) All primary research staff and administrators shall be required to suspend their relationship with any private organizations for the duration of their association with the project. Policy council

members shall be required to suspend their relationship with for-profit organizations which represent a conflict of interest.

(C) These requirements shall include full-time, part-time, or consultant positions with a private organization or other government agencies, and the suspension would include employment, consulting or board membership fees, and stock or business ownership.

(4) The project shall be funded by public, not private monies. Appropriations for the project shall not be diverted from other health care or human service programs.

(5) The project shall, in addition to basic research investigations, operate an on-site clinic to conduct small scale research trials with human participants in such trials are crucial for testing hypotheses related to its basic research.

(b) GOVERNING COUNCIL.—

(1) IN GENERAL.—The project under section 2 shall be governed by, not merely advised by, a council composed of scientists and clinicians representing divergent approaches, and people with AIDS and HIV, and their advocates, from all affected communities. This council shall set policy and oversee re-

search priorities, ethical standards, conflict of interest rules and hiring of researchers.

(2) CERTAIN AUTHORITIES.—The Secretary shall ensure that the following requirements are met with respect to the council under paragraph (1):

(A) The council shall be composed of scientists representing divergent approaches, clinicians with both research and community-based experience and people with AIDS and HIV and their advocates.

(B) The council shall have at least 21 members in order to adequately represent diverse communities, opinions and disciplines. People with AIDS and HIV from diverse communities shall be in the majority to ensure that the project staff are ultimately accountable to people directly affected by the course and outcome of the research. Council members shall step down and be replaced by new members on a regular basis.

(C) The Council shall set policy for and oversee research priorities. It shall develop guidelines for and oversee the hiring of primary research staff, ensuring both high quality (scientific credentials and experience) and a diver-

sity of disciplines and perspectives. Have pursued specific AIDS theories shall not be a necessary prerequisite for hiring. The Council shall have the power to create new research positions when necessary and to remove scientists from their positions after due process and appropriate review of their work.

(D) The Council shall be charged with evaluating the work of the project, as well as the pace of the research, to insure that it matches the urgency of the epidemic. Initially, and throughout the life of the project, the Council, in cooperation with the primary research staff, shall solicit and evaluate all new theories developed outside the Project. It shall direct the Project scientists to evaluate and respond to deserving proposals and to devise new research plans where desirable.

(E) The council shall adopt strict, detained codes governing medical ethics and conflicts of interest and shall monitor compliance with these codes. Project scientists shall report directly to the council about the progress of their work in a manner to be determined by the

council. The council shall report directly to the President about the progress of the project.

(F) Council meetings, including those at which all decisions are made, shall be public and shall be held at least quarterly, with time allotted for public comment. In addition, the Council shall hold an annual public hearing on its priorities and progress. A complete report of the project's goals and accomplishments shall be updated by the Council, submitted to the President and released to the public at least once quarterly. The Council shall evaluate its structure and process at least once per year and make changes which allow it to function more effectively.

(c) COORDINATING COUNCIL.—The Secretary shall ensure that a coordinating committee is established for the project under section 2, in accordance with the following:

(1) The community of scientists selected for the project shall elect three of their members to serve as the coordinating committee for the project, and determine whether these positions should be permanent or rotating.

(2) The coordinating committee shall be responsible for facilitating communication among the dif-

ferent scientists working on the project, for evaluating the progress of its work, and for convening the entire staff on some regular schedule (or when necessary) to evaluate the progress of the project as a whole, reevaluate its direction, and to consider newly developed theories emanating from both within and outside the project.

(3) The coordinating committee shall also be responsible for keeping the policy council informed of the progress of the project's work, at times and in a manner to be determined by the policy council. The coordinating committee shall also make decisions regarding the hiring of research associates, technical staff, purchases of equipment and other day-to-day needs.

(4) The first task of the coordinating committee shall be to facilitate an intensive preliminary review, lasting no more than three months, of all existing pathogenesis hypotheses, as well as other relevant information about AIDS pathogenesis. At the end of this review, the primary research staff shall collectively develop plans for evaluating and testing each of the viable hypotheses, including timelines for evaluating the progress of this work.

SEC. 4. OPEN AND PRODUCTIVE RESEARCH PATHS.

The Secretary, in carrying out the project under section 2, shall ensure that the following requirements are met:

(1)(A) Equal consideration shall be given to conventional and other medical approaches and scientific theories, and researchers representing divergent approaches shall be on the primary research staff well as be contributing researchers.

(B) The project shall aggressively pursue research into all areas of AIDS pathogenesis. The two broad categories of theories to be researched by the project are—

(i) understudied virological/immunological theories about how immune system damage occurs; and

(ii) theories about co-factors which may precede, activate or even substitute for HIV in the process of immune system damage leading to AIDS.

(C) Further work shall be done on the potential role of recreational drugs (including alcohol) in progression. Nutritional research must also be included in the Project. Several chemical and heavy-metal toxins (including cigarette smoke) must be explored. Psychoneuroimmunology and its connections between

psychological stress, lack of social support, and immune compromise, shall be studied.

(D) Examination shall be given to the full spectrum of pathogenesis theories, from those maintaining that HIV is the sole and sufficient cause to those considering HIV a primary cause together with co-factors to those believing that HIV does not necessarily play a causative role.

(E) A diversity of theories should be developed and tested through both laboratory experiments and epidemiological research, including careful examination of existing medical records of people with HIV and AIDS.

(F) Researchers shall research epidemiological and blood studies of long-term survivors from diverse populations to attempt to isolate the factors that have sustained them. Subjective evidence, including asking people with AIDS and HIV and their care providers what factors they think may be playing a role, and how the factors may have interacted, shall be collected to supplement, and help to synthesize quantifiable data.

(G) Consideration shall be given to the hypotheses and results obtained in other countries, and the best and brightest researchers from other

countries shall be aggressively pursued by the project. This may include agreements by another country to reassign particular researchers to the project for an indefinite commitment. The project's progress shall not await the conclusion of such international agreements.

(2) The project's study of AIDS pathogenesis and manifestations must focus on all populations of people with AIDS and HIV. Equal consideration shall be given to the differences between these populations as to their similarities or ''norms''. This includes women, children, gay men, lesbians, people of color (of various affected national-cultural groups), injection drug users, hemophiliacs and people with inadequate medical care and/or nutrition.

(3) Basic science investigations and therapeutic results shall be geared to people at every point on the spectrum of AIDS and HIV—from the sickest to the healthiest. Saving people considered ''near death'' must be considered as important as early intervention.

(4) Information generated by the Project shall be made freely available to researchers, health care providers, people with AIDS and HIV and their ad-

vocates as soon as it is available, without being inhibited by professional publication practices.

(5) Curatives ultimately released due primarily to project research shall not result in financial gain to any private organization, and shall be made available to all affected people regardless of ability to pay.

SEC. 5. EXTRAORDINARY POWERS.

In carrying out the project under section 2, the Secretary shall have extraordinary powers to carry out the following:

(1)(A) Direct the utilization of any and all existing United States Government funded research entities and their facilities to clinically test promising cures developed on the basis of its research and to direct the manner in which such research shall proceed, including staffing, participants, location, and timing. Such research shall be funded by the project.

(B) The project shall design its own protocols and work with these existing clinical trial programs to develop research designs and methods appropriate to the project's goals, assuring that data gathered by the NIH would accurately reflect the use of these compounds in all populations and stages of illness.

(C) The project shall provide funding for these clinical trials of its own compounds. In areas of conflict, the project shall have the power to implement its goals.

(2) Exercise the right of eminent domain to carry out the following:

(A) Obtain from public and private organizations, with just compensation, samples of all potential curatives and all data regarding their development (including safety and efficacy data) as well as other information, materials, or products deemed crucial to the Project.

(B) Implement clinical testing for potential curatives owned by private companies, whether under development or not, unless said companies adhere to an approved time frame and are forthcoming with their data as such work proceeds.

(C) Use existing pharmaceutical company facilities (with just compensation) for the production of promising curatives to be utilized in project research and, if effective, to produce such curatives in sufficient amounts to be disseminated to all people needing them.

(D) If a drug company is found to be impeding or halting the development of a promising compound, the project shall first attempt to work with the company to develop the needed timetable for research and trials. A company lacking the resources to develop a compound shall have the option of selling the compound to the project for a just compensation, or allowing portions of its development to be undertaken by the project.

(E) If, however, a company refuses to cooperate with the project by not releasing needed data, or by withholding samples of requested compounds, the project is authorized to use powers of eminent domain to procure samples and data. The project shall have the power to obtain the patents of such compounds if, after reasonable attempts at cooperation, it finds that a company will not develop a promising compound in an accelerated fashion. After notification by the project that this power will be used, a company shall have 30 days in which to develop, for the project's approval, a plan for accelerated development of the compound to avoid losing its patent.

SEC. 6. PLANNING FUNDS.

Funds shall be allocated immediately to be used for planning of the project under section 2 (including creating facilities, selection of staff, funding, structure, and schedules), so that the project can begin functioning as soon as is possible.

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